

**REMARKS/ARGUMENTS**

This amendment is filed in response to the Office Action dated January 11, 2007. A petition for a three month extension of time, and authorization to charge the fee is submitted herewith.

Claim 1 has been amended to recite that the immersing step forms a "plastic article-first polymer complex". Support for this amendment may be found at page 8, line 27-29.

Claim 1 has been further amended to recite that the first polymer solution has a pH of 4 or less. Support for this amendment may be found at page 7, line 30. Claim 1 has been further amended to recite that the plastic article-first polymer complex is contacted with purified water or a buffer solution comprising a pH of about 7. Support for this amendment may be found in the Examples and particularly at page 12, lines 12-14; page 17, line 30- page 13, line 3; page 19, lines 21-23, page 22, lines 7-9 and lines 27-28; and page 25, lines 2-4.

Claim 8 has been canceled.

New claim 54 has been added. Support for new claim 54 may be found in original claims 1 and 2, and as noted for claim 1 above. Authorization to charge Applicants account for the newly added claim is submitted herewith.

Applicants respectfully submit that the foregoing amendments are fully supported by the specification. Entry of the amendments is requested.

**Rejections under 35 USC §112**

Examiner has rejected claims 1, 3-8, 39-49, and 51-53 under 35 U.S.C. 112, stating that the recitations of "free of coupling agents" and "the step of immersing is prior to any pretreatment" are negative limitations which do not appear to be explicitly disclosed. Examiner has noted that all claims were rejected because of their dependency on claim 1. Accordingly, only claim 1 will be discussed.

MPEP 2173.05 specifically recognizes that negative limitations may be proper and explains, "Any negative limitation or exclusionary proviso must have basis in the original disclosure. \* \* \* Note that lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support."

This application describes the limitation “wherein the surface of said plastic article is not pretreated prior to said immersing and wherein said aqueous solution contains no coupling agents” (a) by not disclosing any pretreatment of the plastic article prior to the immersion of the plastic article in the solution of the polymer having carboxyl-functional groups and (b) by not disclosing the use of coupling agents for coupling the polymer layer to the plastic article substrate. Page 7, lines 13-18, indicates that the results of this invention were surprisingly produced by the “very simple treatment of immersing the plastic articles in at least one kind of aqueous solution,” implying that the invention involves nothing more than the immersion claimed.

“Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date, the applicant was in possession of the invention as now claimed.” *See*, MPEP 2163.01,

However, in the interest of forwarding prosecution, Applicants have amended the claims to delete the negative limitations and recite that the immersing step forms a “plastic article-first polymer complex”. From the specification it is clear that the carboxyl functional polymers form a complex “with the hydrophilic polymers in the hydrogel base material”. Thus, claim 1 as amended is clearly supported by the specification. Withdrawal of the rejection based upon 35 U.S.C. 112 is respectfully requested.

#### **Rejections under 35 USC §102**

Examiner has rejected claims 1,3-5, 7, 10, 13-14, 39-49 and 51-53 as anticipated or obvious in view of McGee et al.

McGee et al discloses removably attaching hydrophilic polymer chains to the surface of a contact lens by “creating a chemical bond between the substrate material and the hydrophilic polymer chains which can be severed without substantial mechanical damage to the substrate.” Page 4, paragraph 62. In McGee et al. “chemical functionality at the surface of the medical device is utilized to covalently attach hydrophilic polymer to the object substrate.” Page 5, paragraph 66, last 3 lines. From the examples the chemical bond is generated via the incorporation of a catalyst (See paragraphs 177, 179, 183, 187 and 190). The pH of the coating solution is not disclosed.

Unlike McGee et al. Applicants have found that a "strong polymer complex" (page 8, line 27) can be formed simply by immersing a plastic article in an aqueous solution having a pH of 4 or less and comprising at least one carboxyl functional polymer. The pH is critical in providing the desired improvement in hydrophilicity. "The treatment with the polymer aqueous solution, having a pH of more than 4 and less than 8, may take a long time to produce the hydrophilicity, and in some cases, sufficient hydrophilicity may not be produced." Page 8, lines 1-3. The pH range is not disclosed in McGee et al. Accordingly, Applicants submit that the claims as presently amended are novel in view of McGee et al.

Examiner has further rejected claim 6 as unpatentable over McGee et al. in view of Masuhara et al. (US 3,988,274). Mashara et al. discloses a process for forming a contact lens. The contact lens polymer of Masuhara et al. comprises an acrylic or methacrylic acid derivative. After the lens is formed the lens is swelled "by hydration treatment including an alkali treatment." Masuhara et al. is absolutely silent with respect to treating a lens with an aqueous solution comprising at least one carboxyl functional polymer. Masuhara et al. also fails to suggest that the aqueous solution should have a pH of 4 or less. The only post treatment suggested by Masuhara et al. is treatment with an alkali solution, which is disclosed to have a pH of 8-12 (column 5, lines 14-16). Clearly claim 6 is patentable over the combination of McGee et al. and Masuhara et al.

Examiner has further rejected claims 8 and 11 as unpatentable over McGee et al. in view of Heiler et al. (US 6,348,507). Claim 8 has been canceled. Heiler et al. discloses plasma treating a silicone hydrogel contact lens and subsequently heating the lens in an aqueous solution containing a surface-protective agent. (Abstract) The surface protective coating is a "silicon-containing agent, for example, a silicate salt, the free acid thereof or a colloidal silicon dioxide" column 5, lines 24-26. The silicon-containing agents are disclosed at column 5, line 31-column 6, line 12. Aqueous solutions of carboxyl functional polymers are not disclosed. Heiler et al. further discloses that the pH of the silicate solutions is "around pH 7, preferably between about 6 to 8." Column 5, lines 52-54. Thus, Heiler et al. discloses an entirely different surface treatment process, with a pH in a range different than that specified in amended claim 1 and new claim 54. Even if one of skill in the art was motivated to take the pH from the silicon-containing coating, and apply it to the process of McGee et

al., the pH range (about 6 to 8) is still outside that recited in amended claim 1 (less than about 4). Applicants respectfully submit that claim 11 is novel over the combination of McGee et al. and Heiler et al.

**Conclusions**

Applicants respectfully submit that the foregoing amendments and remarks have traversed Examiner's rejections. Withdrawal of the rejections, entry of the amendments and allowance of the claims is respectfully requested.

If the Examiner is of a contrary view, the Examiner is requested to contact the undersigned attorney at (904) 443-3074.

Respectfully submitted,

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